K051666

AUG 2 3 2005

510(k) Summary

Submitter

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Contact:	Andrew J W Wall, Quality Manager	
Summary Prepared:	18 April 2005	Rev. 0
Summary Amended:	12 July 2005	Rev. 1

Name of Device

Trade Name:	GAV – General Anaesthetic Vaporizer
Common Name:	Vaporizer
Classification Name:	Vaporizer, Anesthesia, Non-Heated
Product Code:	CAD
Regulation Number:	21 CFR 868.5880

Legally Marketed Device on which equivalence is claimed

Trade Name:	Tec 5 Continuous Flow Vaporizer
Common Name:	Vaporizer
Classification Name:	Vaporizer, Anesthesia, Non-Heated
Product Code:	CAD
Regulation Number:	21 CFR 868.5880
510(k) Number:	K892057

Description of the Device

The GAV – General Anaesthetic Vaporizer is designed for use in continuous flow techniques of general anesthesia. It has a finely graduated dial coupled with an output which remains largely unchanged over a wide range of dial settings, flow rates and temperatures. Safety features such as Interlock, Non-Spill and Keyed Filler are incorporated together with many convenience features which help to ensure reliable and trouble-free operation. GAV vaporizers are agent specific and are clearly labelled and colour coded for additional safety.

Intended Use

Indications For Use:

General anesthesia may be produced using techniques of inhalation anesthesia and in such cases the use of an anesthetic vaporizer such as the GAV will be indicated.

Non-Clinical Performance Data

The pre-market notification references non-clinical tests the results of which are detailed in Section 4.

Summary of Comparisons - GAV v Tec 5

Clinical:

Used for the same clinical purpose
(to induce and/or maintain required depths of inhalation anaesthesia in patients)

Used at the same site in the body
(connected to the patient breathing circuit via the Selectatec system and the common gas outlet of the anaesthetic machine)

Used on similar patient populations
(Ages, anatomy, physiology etc.)

Has similar relevant performance according to expected clinical effect for the specified intended use
(output matches the set concentration and remains constant over a number of changing/changeable variables)

Technical:

GAV used under similar conditions of use
(used in appropriate clinical environments)

Has similar specifications and properties
(Accuracy, temperature range, flow range, pressures and output matches the set concentration and remains constant over a number of changing/changeable variables)

Is of similar design
(Mechanical with single, direct-reading control dial which is calibrated in volumes percent (% V/V), compatible with Selectatec system, integral interlock, keyed filler, liquid level indicator.

Has similar principles of operation
(Variable bypass, flow over with wicks. For use outside the breathing system. Temperature compensation by automatic flow variation. Agent specific)

Manufactured from similar materials
(Specified grades of brass, copper, aluminium, bronze, stainless steel, thermoplastics, PTFE and rubber. Glass, cotton, metal foil. Various adhesives, solder, lubricants and wax. Electroplating and anodizing.)

Biological:

(Connected to the patient breathing circuit via the Selectatec system and the common gas outlet of the anaesthetic machine)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2005

General Anaesthetic Services, Limited
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K051666
Trade/Device Name: GAV – General Anaesthetic Vaporizer
Regulation Number: 21 CFR 868.5880
Regulation Name: Anaesthetic Vaporizer
Regulatory Class: II
Product Code: CAD
Dated: August 11, 2005
Received: August 15, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not yet known

Device Name: GAV – General Anaesthetic Vaporizer

Indications For Use:

The GAV General Anesthetic Vaporizer is a concentration-calibrated device intended to deliver specific anesthetic agents into the fresh gas supply of an anesthesia workstation or anesthesia gas machine. The volatile agents intended to be used with this device are: Isoflurane, Sevoflurane and Halothane.
US Federal law restricts this device for sale by or on the order of a licensed physician

Prescription Use *Applicable* (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use *Not Applicable* (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna Sullivan

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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